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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,449	03/28/2000	KATSUMI AOYAGI	594.352USWO	8016

7590 02/23/2005  
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/509,449

Applicant(s)

AOYAGI ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12-14-04</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

1. Currently, claims 18-22 are pending and under consideration. These claims were rejected in the prior action, mailed on July 28, 2004. In the Response filed on January 27, 2005, the Applicant amended claims 18-20, and 22.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on December 14, 2004, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### ***Claim Objections***

3. **(Prior Objection- Withdrawn)** Claims 19 and 20 were objected to because of the following informalities: it is unclear why the claims refer to both the HCV polyprotein and parenthetically to the HCV core antigen. In view of the amendment of the claims, the objection is withdrawn.

### ***Claim Rejections - 35 USC § 112***

4. **(Prior Rejection- Withdrawn)** Claims 18- 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because it was unclear what was meant by the “and/or” in the claimed method “for determining the presence of Hepatitis C virus (HCV) core

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antigen and/or anti-HCV core antibodies in a sample.” In view of the cancellation of this language from the claim, the rejection is withdrawn.

**(Prior Rejection- Withdrawn)** Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendment of the claim, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **(Prior Rejection- Maintained)** Claim 18 was rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Masalova et al., J Med Virol (of record in the action mailed on September 27, 2001) in view of Papatheodoridis et al. (J Hepatol 24: 36-41), and further in view of the teachings of Ling et al. (GB 2 051 357), and of Schönbrunner (GB 2 313 666). The Applicant traverses the rejection on the basis of deficiencies in either of Ling or of Schönbrunner. In particular, the Applicant argues that Ling does not specifically disclose a non-complementary pair of immunoreactants based on different epitopes on the same protein, and that Schönbrunner does not teach the detection of both an antigen and an antibody at the same time in the same vessel. These arguments are not found persuasive.

With respect to both of the arguments, it is noted that the rejection is not based on the teachings of any one of the cited references, but on the knowledge of those on the art as indicated by the combination of each of the cited references. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Because the current rejection is based on the combined teachings of the cited references, the arguments relating to the failure of any one of the Ling or Schönbrunner references are not found persuasive.

With respect to the asserted failings of the Ling reference, while the reference discloses the use of a particular set of immunoreactants, the teachings of the reference are not limited to that set. Rather, the reference teaches “other combinations of non-complementary immunoreactants ... may be employed.” Pages 2. The reference indicates that the only limitation on which immunoreactants may be used is that each of the immunoreactants must be non-complementary, i.e. the first antibody (used to detect the second, sample antigen) must not bind to the first peptide (used to detect the second antibody found in the sample). *Id.* Schönbrunner further teaches that multiple epitopes may be found on the same protein antigen. Based on these combined teachings, it would have been obvious to one of ordinary skill in the art, that a first antibody that binds to a epitope not found in the first peptide, but that may be found on the same protein antigen from which the peptide was derived, may be used in combination with the first peptide. As indicated by Ling, the only requirement is that the first antibody does not bind to the first peptide. For this reason, the Applicant’s arguments with respect to Ling are not found persuasive.

The Applicant's argument with respect to Schönbrunner are also not found persuasive because, while Schönbrunner may not teach the claimed method, any teachings not found in Schönbrunner may be found in the teachings of Ling, or in the suggestion based on Ling and Masalova.

For these reasons, and the reasons of record, the Applicant's arguments in traversal are not found persuasive, and the rejection is maintained.

7. **(Prior Rejection- Maintained)** Claim 18 was rejected under 35 U.S.C. 103(a) as being unpatentable over Simmonds et al. (WO 93/10239) in view of Ling and Schönbrunner. Claim 18 has been described above. The Applicant traverses this rejection for substantially similar reasons to those presented with respect to the rejection over Masalova, Papatheodoridis, Ling, and Schönbrunner above. These arguments are not found persuasive for substantially the same reasons as indicated above. I.e., the deficiencies of Ling are resolved by the combination of Ling with Schönbrunner, and the deficiencies of Simmonds are resolved by the combination of the teachings of Simmonds (noting the deficiencies with screening for only antibodies or only a protein of HCV) with the teachings of Ling (noting the benefits of screening for both the antibody and the antigen simultaneously). For these reasons, and the reasons of record, the rejection is maintained.

8. **(Prior Rejection- Maintained)** Claims 19 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Masalova and Papatheodoridis, or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further in view of either Lacroix (EP 0

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507 615) or Seidel et al. (U.S. Patent 6,183,949). The Applicant traverses this rejection on the basis that Lacroix and Schönbrunner fail to cure the deficiencies asserted by the Applicant with respect to claim 18 above. Because these arguments were not found persuasive with respect to claim 18 for the reasons above, the argument is also not found persuasive with respect to claims 19 and 20. The rejection is therefore maintained for the reasons above, and the reasons of record.

9. **(Prior Rejection- Maintained)** Claims 21 and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Masalova and Papatheodoridis or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further in view of either of either Cheng et al. (U.S. 5,627,080) or Khanna et al., (U.S. 5,032,503). The Applicant traverses this rejection on the basis that Lacroix and Schönbrunner fail to cure the deficiencies asserted by the Applicant with respect to claim 18 above. Because these arguments were not found persuasive with respect to claim 18 for the reasons above, the argument is also not found persuasive with respect to claims 19 and 20. The rejection is therefore maintained for the reasons above, and the reasons of record.

### ***Conclusion***

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

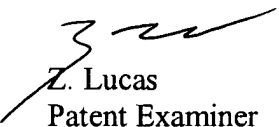
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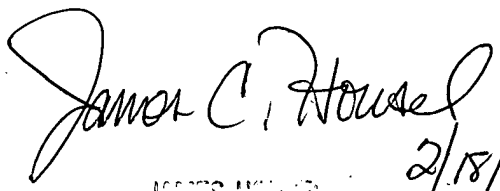
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Z. Lucas  
Patent Examiner

  
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2/18/05